

REMARKS

Claims 1 to 16, 28 to 36, and 61 to 64 are pending, and claims 1 to 15, 36, 61, and 62 have been withdrawn from consideration. Claims 16, 28 to 35, 63, and 64 are under examination.

Claim rejections – 35 U.S.C. § 102(e)

The Examiner has rejected claims 16, 28 to 30 and 33 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,263,236 to Kasinkas et al. (Kasinkas). Applicant respectfully traverses this rejection of the claims and requests that the Examiner reconsider the rejection based upon the remarks that follow.

Claims 16 and 28 are the only pending independent claims. Each is directed to a device for removing material from a vessel wall at a vascular site. The device includes a cage and a material removing element. The cage has a plurality of openings and an inner surface which defines a cavity. The cage is moveable from a collapsed position to an expanded position. The cage is configured such that when the cage is in the expanded position at the vascular site material from the vessel wall extends from the vessel wall into the openings. The cage is releasable so that the cage may be left within the patient. The material removing element is positioned within the cavity and is configured to be moveable along the inner surface of the cage to remove material from the vessel wall which extends through the openings. Claim 16 further recites that the plurality of openings are formed by rigidly connected elements.

In rejecting claim 16 the Examiner states that Kasinkas discloses a cage 18 which is moveable from a collapsed position to an expanded position, the cage having a plurality of openings in the expanded position, the openings being formed by rigidly connected elements 20b. The Examiner further states that the cage is configured such that when in

the expanded position material from the vessel wall extends from the vessel wall into the openings and that the cage is releasable so that the cage may be left within the patient. The Examiner notes, however, that the limitation “the cage may be left within the patient” is an intended use and does not impose any structural limitations on the claims distinguishable over Kasinkas, which is capable of being used as claimed. The Examiner states that Kasinkas includes a material removing element 20c positioned within the cage to remove the material from the vessel wall extending into the cage when the cage is in the expanded position. The Examiner states that the material removing element is configured to be movable along the inner surface of the cage to remove the material extending into the openings and cites to Kasinkas, col. 6, lines 15 to 20 in support of that statement.

Applicant respectfully submits that the rejection of claim 16 must be withdrawn for numerous reasons. For example, claim 16 is directed to a device which is comprised of a number of elements including (1) a cage having a plurality of openings formed by (2) rigidly connected elements, and (3) a material removing element positioned within the cage cavity. The Examiner has rejected claim 16 as being anticipated by Kasinkas. Specifically, the Examiner states that Kasinkas discloses a cage 18 having a plurality of openings formed by rigidly connected elements 20b and a material removing element 20c positioned within the cage cavity. Applicant respectfully points out to the Examiner that element 20b is one form of an expansion mechanism shown, for example, in the embodiments of FIGS. 7 and 8 having cage wires 32 that are expanded by retraction of a pull wire 34. (Kasinkas, col. 5, lines 5 to 9). Element 20c are a shape memory expansion mechanism of a separate embodiment shown, for example, in FIGS. 9 and 10. (Kasinkas, col. 5, lines 16 to 29). None of the embodiments disclosed by Kasinkas include both elements 20b and 20c. This is understandable since elements 20b and 20c are merely alternatives of the same element. Kasinkas does not disclose nor teach that elements 20b

and 20c would be used together in the same embodiment. Since these elements provide the same function there would clearly be no reason to do so. This rejection is, therefore, improper because it is based on a combination of features of different embodiments of the same reference.

Claim 16 is allowable for an additional reason. Claim 16 is directed to a device which includes a cage which is “releaseable so that the cage may be left within the patient”. To the extent that the Examiner believes this is merely a statement of intended use imposing no structural limitations the Applicant disagrees. A person of skill in the art would clearly understand the term “releaseable” to be a structural feature of the cage. The person of skill in the art would further understand the phrase “so that the cage may be left within the patient” to further define the term “releaseable” in terms of that structural feature. Kasinkas does not disclose or teach a device having a cage which is “releaseable so that the cage may be left within the patient”. Distributor 18, which the Examiner identifies as the cage, is not shown or described in any of the embodiments disclosed by Kasinkas as being releaseable from the device or as being capable of being left within the patient after the device is used. Therefore, the device disclosed by Kasinkas does not anticipate claim 16 for at least this reason.

Claim 16 includes additional limitations not disclosed or taught by Kasinkas. Claim 16 requires a “material removing element” positioned within the cage. The Examiner indicates that element 20c comprises a material removing element. However, Kasinkas describes 20c as a shape memory expansion mechanism which is connected to catheter body 12 and surrounded by distributor 18. Expansion mechanism 20c functions to expand to bring the distributor into close proximity with the vessel wall. Neither the expansion mechanism 20c nor any other portions of the device disclosed by Kasinkas function to remove material. Rather, the object of the device is to provide a catheter that can deliver light, heat, or a therapeutic agent to a target region in a vessel wall without

occluding blood flow in the vessel (Kasinkas, col. 1, lines 59 to 62). Therefore, Kasinkas does not have a material removing element as required by claim 16.

Even if one were to improperly conclude that the expansion mechanism 20c of Kasinkas comprises a material removing element claim 16 still distinguishes over Kasinkas because it requires that the material removing element be “configured to be moveable along the inner surface of the cage to remove the material extending into the openings”. Kasinkas does not disclose or teach that the expansion mechanism 20c moves along an inner surface of the distributor 18 in the manner required by claim 16. The portion cited by the Examiner (Kasinkas, col. 6, lines 15 to 20) indicates that the distribution elements can expand or contract in response to the expansion mechanism. Clearly, that is the function of the expansion mechanism. The cited passage does not, however, support the conclusion that the expansion mechanism is configured to be moveable along an inner surface of the distributor 18 to remove material extending into openings in the distributor. For this additional reason Kasinkas does not have a material removing element configured in the manner required by claim 16.

Claim 28 is not anticipated by Kasinkas for reasons similar to those discussed above in connection with claim 16. For example, claim 28 is directed to a device which includes a cage which is “releaseable so that the cage may be left within the patient”, a “material removing element” positioned within the cage which is “configured to be moveable along the inner surface of the cage to remove the material extending into the openings”. For the same reasons discussed in detail above and incorporated herein by reference, Kasinkas does not disclose or teach these features and, therefore, does not anticipate claim 28. Claims 29, 30 and 33 depend from claim 28 and add further significant limitations and are allowable for at least the same reasons as claim 28.

Claim rejections – 35 U.S.C. § 103(a)

The Examiner has rejected claims 31, 32, 63 and 64 under 35 U.S.C. § 103(a) as being unpatentable over Kasinkas in view of U.S. Patent No. 5,100,423 to Fearnot. Applicant respectfully traverses this rejection. The Examiner has further rejected claims 34 and 35 under 35 U.S.C. § 103(a) as being unpatentable over Kasinkas.

Claims 31, 32, 34 and 35 depend from claim 28 and claims 63 and 64 depend from claim 16. Fearnot does not correct any of the deficiencies of Kasinkas as discussed above in connection with claims 16 and 28. Therefore, claims 31, 32, 34 and 35 are allowable for at least the same reasons as claim 28 and claims 63 and 64 are allowable for at least the same reasons as claim 16. Some of these claims are, however, allowable for at least an additional reason.

Claims 31 and 63 are similar except claim 31 depends from claim 28 and claim 63 depends from claim 16. These claims further require a “collapsible bag positioned to receive the material removed by the material removing element”. The Examiner states that Kasinkas teaches all limitations substantially as claimed except a bag positioned to receive the material. The Examiner states that “Fearnot teaches the bag or net . . . in order to capture debris or matter from the bag or the filter” and concludes that it would be “obvious to one having ordinary skill in the art at the time of the invention to modify Kasinkas by adding the bag or the net as taught by Fearnot in order to capture debris or matter from the bag or filter.” Applicant traverses this rejection and submits that a person of skill in the art would have no reason to modify Kasinkas in the manner suggested by the Examiner. Initially, Applicant submits the Examiner’s conclusion that it would be obvious to add a “bag or net” to capture debris from a “bag or filter” is somewhat confusing. Claims 31 and 63 require a collapsible bag to receive material removed by a “material removal device”. As set forth above, the object of the device disclosed by Kasinkas is to provide a catheter that can deliver light, heat, or a therapeutic agent to a

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Applicant: Stephen W. Boyd
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target region in a vessel wall without occluding blood flow in the vessel (Kasinkas, col. 1, lines 59 to 62). Kasinkas does not include a material removal device since it is not concerned with removing material from the vessel. Since Kasinkas does not remove material a person of skill in the art would have no reason to add a bag to the device since there is no material to be received by the bag. For this additional reason claims 31 and 63, and claims 32 and 64 which depend therefrom, are allowable.

In view of the foregoing Applicant submits that all of the pending claims are allowable and requests that the rejections be withdrawn.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

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By /Terry L. Wiles/

Customer No. 009561

Terry L. Wiles (29,989)

Patrick J. O'Connell (33,984)

Popovich, Wiles & O'Connell, P.A.

650 Third Avenue South, Suite 600

Minneapolis, MN 55402

Telephone: (612) 334-8989

Attorneys for Applicant

twiles@pwolaw.biz